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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

| EXAMINER | |
|---|---|
| LEFFERS JR, GERALD G | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1636 | |

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/720,252 | HELIBRONN, REGINE | |
| | Examiner | Art Unit | |
| | Gerald G. Leffers Jr., PhD | 1636 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *60-79* is/are pending in the application.

4a) Of the above claim(s) *60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/7/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Receipt is acknowledged of an amendment to the claims, filed 12/30/2004, in which several claims were cancelled (claims 32-59) and in which several new claims were added (claims 61-79). Receipt is also acknowledged of a response filed on 11/30/2004 in which arguments concerning the rejections of record in the office action mailed 7/1/2004 were presented. Many of these arguments are addressed below. Claims 60-79 are pending in the instant application, with claim 60 being withdrawn from consideration as being directed to a nonelected invention.

Any rejection of record not addressed herein is withdrawn. This action is FINAL.

### *Information Disclosure Statement*

Receipt is acknowledged of an information disclosure statement (IDS) filed on 12/7/2004. The signed and initialed PTO Form 1449 has been mailed along with this action. All references were considered. Several references are lined-through on the PTO Form 1449 in order to prevent their duplication on the face of any patent to issue from the instant application.

### *Claim Objections*

Claims 61-62 & 70 are objected to because of the following informalities: each of the claims refers to a "wild type" or "wild-type" herpesvirus. While each spelling of the term "wildtype" is acceptable, it would be less confusing if a consistent spelling were used throughout the claims. Appropriate correction is required.

Claim 65 is objected to because of the following informalities: the claim is grammatically incorrect in that there is an article (e.g. the, a or an) missing between the words "lacks" and "UL9 gene". Appropriate correction is required.

Amended claim 69 recites the limitation "the rHSV of claim 61 which is a recombinant HSV-1 strain 1802", which is grammatically incorrect. HSV-1 strain 1802 cannot be the rHSV of claim 61 because, as is made clear in the rest of claim 69, it does not normally possess the sequences encoding the Rep and Cap gene products. While this does not make the metes and bounds of claim 69 indefinite, it does make the claim somewhat confusing. It would be remedial to amend the claim language to recite "the rHSV of claim 61 which is a recombinant derivative of HSV-1 strain 1802".

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 61-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These are new rejections that were necessitated by applicant's amendment of the claims in the response filed on 12/30/2004.**

Claims 61-62 & 70 specifically recite the term "wild type" or "wild-type". The claims are vague and indefinite in that it is not clear what reference virus genome is encompassed by this term. This is due to the fact that the replication-defective virus of the invention comprises at least two different alterations from what might be considered as a "wildtype" genome (i.e.

inactivation of at least one nonessential gene and insertion of the sequences encoding Rep and Cap in a non-essential region of the rHV genome). Even if one were to insert the term "corresponding" wildtype HV (as is supported in the specification at page 6, lines 26-32), it would still be unclear whether the term necessarily referred to a native HV sequence lacking mutations or to one comprising all of the same mutations as the rHV of the invention except for the loss of the *rep* and *cap* gene sequences. If this latter interpretation of the term "wildtype HV" is correct, it would be remedial to amend the claim to clearly recite that it is the corresponding RV sequence lacking the *rep* and *cap* gene sequences.

Claim 69 recites the limitation "rHSV". There is no clear and positive prior antecedent basis for the term in claim 61, upon which claim 69 is dependent. It would be remedial to change the dependency for claim 69 to claim 67, which recites the limitation that the HV of claim 61 can be rHSV.

Claim 75 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term "the host cell" in claim 73, upon which claim 75 is dependent.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 61-79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

**This is a new rejection that was necessitated by applicants' amendment of the claims in the response filed on 12/30/2004.**

Claim 61 has been amended to recite the limitation of an "expression vector" inserted into a non-essential region of recombinant herpesvirus genome and to further recite the limitation "wherein no visible reversion to wild type HV under replication conditions is observed as determined by a plaque assay". Claims 69-70 & 73 also specifically recite that an "expression vector" is inserted into the genome of the rHV. The response filed on 11/30/2004 argues at page 5, 2nd paragraph, that there is support at various locations throughout the specification for these changes (e.g. at page 5, lines 9-17; page 6, lines 18-32; page 7, lines 31-38 to page 8, lines 1-3; the Working Examples and in originally filed claims 1-28).

Contrary to this assertion, there does not appear to be literal support any where in the originally filed specification and claims for broadly reciting that there is an "expression vector" encoding Rep and Cap that is integrated into the genome of the rHV. The term "expression vector" implies an autonomous construct that is capable of self-replication. The specification appears to make clear that what is inserted is only a portion of an expression vector that includes sequences that encode AAV Rep and Cap proteins (e.g. an "expression cassette"; see the working examples where the expression cassette encoding Rep and Cap is excised from pSub2011ac and inserted into HSV-1 1802) to generate the exemplified HSV/AAV hybrid virus of the instant application. It would be remedial to amend the claim language by replacing the term "expression vector" with the term "expression cassette".

With regard to the limitation, "wherein no visible reversion to wild type HV under replication conditions is observed as determined by a plaque assay", there does not appear to be

support for broadly reciting that there is no visible reversion to wild type HV under replication conditions. This recitation is broad in that the specification makes clear that determination that the recombinant virus is genetically stable is determined after "several consecutive dilution steps in a plaque purification" (e.g. page 6, lines 17-32). It would be remedial to amend the claim language to indicate that the reversion is determined after a minimum number of consecutive dilution steps in a plaque assay as is specifically recited in the instant specification at page 6, lines 18-26 (e.g. after 3, 5 or 7 dilution steps).

Claim 62 recites the limitation that titers of the rHV are obtained under culture conditions that are "up to 20%" of the titer of wild-type herpes virus as determined by cell release virus titer. There is no literal or implicit support in the originally filed specification or claims for the limitation of "up to 20%" of the titer of wild type HV. Rather, the instant specification provides support for the limitation of equal to or greater than 20% of the titer of wild type HV (e.g. see page 6, lines 26-32). It would be remedial to amend the claim language for claim 62 accordingly.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 69 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which

it is most nearly connected, to make and/or use the invention. **This rejection is maintained for reasons of record in the office action mailed on 7/12/2004 against claim 40, and which are repeated below.**

The application discloses HSV-1 strain 1802 that is encompassed by the definitions for **biological material** set forth in 37 C.F.R. § 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§ 1.801 through 1.809.

It is unclear whether this biological material is known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. § 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological material. In order for a deposit to meet all criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. §§ 1.801-1.809, in the form of a declaration or applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. § 1.804). Such a statement need not be verified if the person

is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

***Response to Arguments***

Applicant's arguments filed 11/30/2004 have been fully considered but they are not persuasive. The response essentially argues that herpes simplex virus strain HSV 1802 was known in the art at the time of filing (i.e. McGeoch, et al) and can be readily accessed and used by those of skill in the art to insert the AAV *rep* and *cap* gene sequences into the HSV-1 genome because there is ample guidance to do so. For example, the AAV genome sequence is numbered according to GenBank Accession No. J01901 (e.g. see instant specification at page 12, line 35)

This argument is not persuasive in that applicant's claim specifically recites a particular strain of HSV-1 that has a particular genomic nucleic acid sequence. It is not at all clear based upon the art of record that the nucleic acid sequence for strain HSV 1802 was available to the public at the time of filing. Thus, in order for the skilled artisan to be able to make and use the specifically recited strain of HSV-1, the strain must be available to the public for the term of any patent issued from the rejected claim. There is no guarantee of record that HSV 1802 is and will continue to be available to the public in order to make and use the claimed invention. Therefore, applicant is required to deposit the recited biological material in order to enable the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61-64, 67-68, 70-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Dong et al (WO 95/06743; reference AG on IDS #5 submitted by applicant; see the entire reference). **This rejection is maintained for reasons of record in the office action mailed 7/1/2004 against claims 32-39 &41-60, which are repeated below.**

Dong et al teach the construction of helper viruses for production of rAAV that comprise genes essential for AAV replication (e.g. Abstract). Dong et al teach that the helper viruses of their invention can be obtained from adenovirus or one of several different types of viruses classified in a general class of "herpesvirus", including HSV (e.g. page 6, lines 16-28). Dong et al teach that these helper viruses can either be replication competent (i.e. comprising viral packaging and origin of replication sequences) or replication defective (e.g. page 15, lines 19-29). Dong et al specifically teach that the herpesvirus helper viruses of their invention will, generally speaking, comprise one or more of the AAV *rep*, *lip* and *cap* genes (e.g. page 7, lines 8-20). Dong et al teach that the essential or non-essential genes from the helper virus genome have been deleted (e.g. page 7, lines 21-32). Dong et al teach that the helper viruses of their invention can promote expression of the essential AAV genes with either natural AAV promoters (e.g. p5 from AAV) or heterologous promoters (e.g. IE from CMV, retroviral LTR

elements) (page 8, lines 20-27; page 9, lines 4-14). The reference teaches that the nature of the herpes family virus is not believed to be crucial to the successful practice of the invention (e.g. herpes simplex virus, cytomegalovirus, etc.) (page 32, line 20 to page 33, line 9). Dong et al teach a prophetic example for insertion of AAV *rep*, *lip* and/or *cap* sequences into the genome of HSV feature the HSV vector R7020. R7020 features deletion of approximately 700 bp from the domain of the thymidine kinase gene and all of the sequences from the 3' end of the IE63 gene (a27) to the a4 gene in the reiterated sequences of the S component of the HSV genome. Dong et al teach that the *rep-lip-cap* sequences can be inserted in, at least, either of two positions including the site between the inserted tk gene and the HSV-2 DNA sequences and the site of the deletion of the natural tk gene (e.g. Example VI(1), page 44).

***Response to Arguments***

Applicant's arguments filed 11/30/2004 have been fully considered but they are not persuasive. Each of the new claims recites the limitation that the rHV is replication-defective and exhibits no visible reversion to wild type HV under replication conditions as determined by plague assay. At least one of the new claims recites a specific level of titer relative to wild type virus (at least 20% of wild type HV). The response essentially argues: **1)** there is so much information disclosed in the teachings of Dong et al that it is difficult to pick and choose exactly how to make any particular recombinant herpes virus for use in preparing quantities of recombinant adeno-associated virus, **2)** the guidance provided by Dong et al is so general that aside from engendering an undue amount of experimentation to arrive at Applicant's results, there is no explicit teaching to make and use the recombinant herpes virus claimed by Applicant, **3)** Dong et al's assertions regarding the applicability of their teachings concerning recombinant

adenovirus to constructing recombinant herpesvirus are not supported, **4)** the little direction in making rHV constructs and the working example would reasonably result in a HV construct different from that which is claimed, **5)** Applicant was aware of the Dong et al application, that Dong et al outlined in detail an adenovirus construct containing a recombinant insert that included AAV *rep* and *cap* genes, **6)** Applicant has identified a reference in Dong et al (column 8, lines 8-20) describing purification of rAAV where contaminating adenovirus (not herpesvirus) was removed during the purification procedure, **7)** while Figure 7 of Dong et al teaches an adenoviral-based system for production of transducing rAAV using an infection method, the method is not herpesviral-based and Applicant has recognized a potential problem with recombination, **8)** one skilled in the art would recall that most of Dong et al's description of constructs were for recombinant adenovirus, **9)** Example VI of Dong et al teaches the insertion of *rep/lip/cap* genes in the genome of the herpes helper virus and there is no direction to make a herpes virus construct comprising only *rep* and *cap* genes, and **10)** the prophetic embodiment taught by Dong et al features the deletion of a portion of the *tk* domain and all of the region from the 3' end of the α27 gene to the promoter region of the α4 gene, and further features replacing the ITRs with a DNA fragment encoding viral glycoproteins G, D and I, which is distinct from applicant's construct that optionally lacks the ITRs but does not replace them with those particular proteins. The response further asserts that Dong et al does not anticipate the claimed invention because the herpesvirus constructs of the instant application do not undergo detectable homologous recombination as determined by plaque assay and are useful for high titer rAAV production.

The skilled artisan would have readily understood that the generic teachings by Dong et al regarding construction of different types of herpesvirus vectors were and are applicable to each of the different types of herpesvirus taught by Dong et al (e.g. adenovirus, cytomegalovirus, herpes simplex virus, etc.). For example, the skilled artisan would readily have understood that the teaching that the recombinant herpesvirus constructs of Dong et al could be replication defective or replication competent applied to each of the particular herpesvirus constructs specifically contemplated in the Dong et al disclosure, including HSV. With regard to the specifically recited limitation that the rHV vector of the instant claims is replication-defective, there is no limitation in the rejected claims as to under what conditions the vector is replication defective. The skilled artisan would have readily recognized, for example, that the prophetic *tk*- rHV taught by Dong et al in Example VI of their specification would be replication deficient in TK- host cells.

In response to applicant's argument that the reference constructs fail to possess certain features of applicant's invention, it is noted that the features upon which applicant relies (e.g. Dong et al's rHV constructs are not limited to inclusion of only *cap* and *rep* genes but also comprise the *lip* gene; Dong et al's exemplified rHV construct comprises additional genes inserted in the Us region that are not present in applicant's invention) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). For example, the rejected claims use open claim language with regard to what can be inserted into the rHV genome. Further, Dong et al teach that the rHV

constructs of their invention can comprise *any combination* of the *rep/lip/cap* genes (e.g. page 7, lines 8-20).

With regard to the specifically recited limitation that the replication-defective rHV exhibits no visible reversion to wild type HV under replication conditions as determined by a plaque assay, applicant asserts that the rHV constructs taught by Dong et al would not exhibit this property without providing any rational as to why applicant's rHV construct would possess such a property whereas the vector taught by Dong et al does not. As a first matter, the replication conditions are not defined in the claim and the nature of what is intended by the term "wild type" is not clear (e.g. see the 112 2nd rejection above). For example, if the vector taught by Dong et al were grown in TK+ host cells, why would there be an expectation that the vector would somehow revert to "wild type" (e.g. lose the *rep/lip/cap* expression cassette)? If applicant's argument is that Dong et al have not reduced to practice an rHV construct exhibiting this property concerning reversion to wild type, it is noted that applicant also does not appear to have reduced the claimed invention to practice (i.e. the exemplified rHV construct taught in the working examples of the instant application is replication competent and does not appear to require growth in a packaging cell that provides some essential HV gene product in trans). With regard to this limitation, as well as to the limitation that the titer of the rHV obtained under culture conditions that are up to 20% of wild type, applicant's response has made no persuasive argument or presented no data that demonstrates the replication-defective rHV taught by Dong et al would not also have these properties.

Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a

novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See in re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et al (WO 95/06743, 9 March 1995; see the entire document) in view of Dargan et al (U.S. Patent No. 5,994,116 A; see the entire patent). **This is a new rejection that is necessitated by applicant's amendment of the claims in the response filed on 12/30/2004.**

The teachings of Dong et al are described above and are applied as before, except:

Dong et al do not explicitly teach that their replication-defective recombinant herpesvirus (rHV) lacks the UL9 gene.

Dargan et al (the '116 patent) teaches the construction and use of novel herpesviral particles, pre-viral DNA replication enveloped particles (i.e. PREPS; e.g. see the Abstract). The '116 patent teaches that UL9 is one of several HSV-1 genes known to be required for DNA synthesis, and which are thus essential genes (e.g. Example 3, column 8, lines 45-67). Dargan et al further teach the construction of a cell culture line, A26, which expresses the HSV-1 genes

UL6, UL7, UL8, UL9 and UL10. This cell line was able to support the growth of UL8- or UL9-deficient HSV-1 strains (e.g. Example 3, lines 27-48).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Dong et al with regard to construction of a replication-defective rHV expressing the Rep and Cap gene products of AAV to include the deletion of a region of the rHV genome encompassing the UL9 gene because Dong et al teach it is within the skill of the art to construct replication-defective herpesvirus vectors that express essential gene products for AAV replication and because Dargan et al teach it is within the skill of the art to construct packaging cells that provide gene products essential for HSV replication in trans (e.g. UL9). One would have been motivated to do so, as taught by Dong et al, in order to make and use a replication-defective rHSV/AAV virus that does not itself undergo replication in the cells in which its job is to provide the Rep, Lip and/or Cap gene products in trans for packaging of rAAV virions. Absent any evidence to the contrary, there would have been a reasonable expectation of success in making and using a UL9-deficient strain of rHV/AAV from the combined teachings of Dong et al and Dargan et al to produce high titer stocks of rAAV virions.

With regard to reversion to wild type virus under replication conditions, the metes and bounds of what is intended by the term "wild type" HV are not clear (see above). Further, the nature of the replication conditions and the number of serial dilutions required in order to observe reversion are not specified. For example, there is no reason to expect that the rHV/AAV constructs taught by Dong et al would necessarily lose the *rep* and *cap* genes by some sort of recombination process.

Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See in re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

***Examiner's Note***

It is noted WO 95/06743 claims priority to U.S. Application Serial No. 08/114,595, which issued recently as U.S. Patent No. 6,686,200 B1. In the interest of compact prosecution, a rejection has not been made over U.S. Patent No. 6,686,200 B1 since the patent teaches the same invention as that taught in the PCT document and the grounds of rejection would be identical to those already of record. It is noted that applicant was already aware of the '200 patent in that their response to the rejection of several claims under 35 U.S.C. 102(b) as being anticipated by Dong et al (WO 95/06743) actually cites column and line numbers from the '200 patent (e.g. column 23, line 50 as cited on page 9 of the 11/30/2004 response).

***Conclusion***

No claim is allowed.

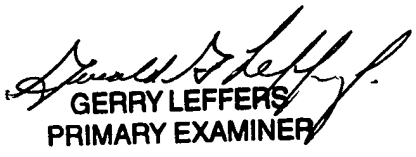
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G. Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).




Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

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